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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/543,007

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Franz Freudenthal

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32047

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05/07/2010

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EXAMINER

OU, JING RUI

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/543,007	<b>Applicant(s)</b> FREUDENTHAL, FRANZ	
	<b>Examiner</b> JING OU	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 40-63 and 65-75 is/are pending in the application.
- 4a) Of the above claim(s) 74 and 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-63 and 65-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This action is responsive to the preliminary amendment filed on 02/22/2010. Claims 40-63 and 65-75 are pending. Claims 40, 67, 71, and 74 are independent. Claims 74 and 75 are withdrawn from consideration.

#### ***Claim Objections***

2. Claim 51 is objected to because of the following informalities: the recitation that the wire-like element includes two ends is already claimed in Claim 40. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 46, 48-50, 55, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 recites the limitation "the area of application" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 48 recites the limitations "the material concentration" and "the material thickness" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

The recitation "wherein partial areas of the support structure are formed from a wire-like element having different diameters" in Claim 49 is unclear whether it is the same as "said single wire-like element" as recited in Claim 1. In addition, the recitation "wherein partially different diameters of the wire-like

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element of the support are formed by provision of several wires" in Claim 49 is self-contradictory to the claimed limitations in Claim 40.

Claim 50 recites the limitation "the amount of wire-like element" in line 1-2 of the claim and "a concentration of wire-like element" is unclear whether the wire-like element is the same wire-like element as recited in Claim 40.

In Claim 55, it is unclear that how individual parts of the support structure are designed uniformly while corresponding to one another or differing from one another.

Claim 62 recites the limitation "said edge area" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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7. Claims 40-59, 63, 65, and 66 rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz et al (US Pat. No.: 5,944,738) in view of either Andersen et al (US Pat. No.: 5,876,445) or Shaw et al (US Pat. No.: 6,171,329).

In regard to Claims 40-59, 63, 65, and 66, Amplatz et al discloses a device comprising: a support structure (10) which has a primary shape which as a first length-to-width ratio along an axis in a primary shape (Fig. 5) and having secondary shape having second length-to-width ratio along said axis in a secondary shape (Fig. 7), a proximal portion, and a distal portion (12 and 14); wherein said first length-to-width ratio is greater than said second length-to-width ratio; wherein the proximal portion/and or distal portion in the secondary shape is substantially flat in a disk shape (Fig. 7); and a delimited inner space (Fig. 5); wherein the proximal portion and the distal portion are placed flat and partially on top of one another (Fig. 2); wherein at least a partial area of the implantable device is folded (Fig. 5); wherein an eccentrically arranged central through-opening (the central channel space formed in the device) remains in the implantable device in the secondary shape of the support structure (Fig. 7); wherein an intermediate portion (16) having a reduced diameter compared to the proximal portion and distal portion (Fig. 5); wherein the primary shape is asymmetrically or irregularly configured (Fig. 5); wherein the material concentration inside the support structure is different from portion to portion (Fig. 5, the material concentration inside the support structure is different from the proximal end to the central portion); wherein the end of the proximal portion is completely close by provision of a plate element (30); the end of the distal portion

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or proximal portion has one or more loops which are interlaced in particular with a substantially uniform edge being formed (Fig. 7); wherein the support structure is designed as a two-part unit (12 and 14) connected to one another to form one part; wherein individual parts of the support structure are designed uniformly (Fig. 7); the support structure of the implantable device in the primary shape is configured like a stent (a stent can have any shape); wherein one or more membranes are incorporated into the support structure (Col. 9, lines 55-58); wherein the membrane is formed by inweaving of at least one filament (a mesh is formed by inweaving of at least one filament); and wherein the wire-like element of the implantable device is made of nitinol (Col. 5, lines 48-60).

Amplatz et al does not appear to disclose that the support structure is formed from a single wire-like element. However, Andersen et al teaches a support structure of an implantable device formed from a single wire-like element (Andersen et al, Col. 8, lines 30-31). In addition, Shaw et al teaches a support structure of an implantable device formed from a single wire-like element (Shaw et al, Col. 13, lines 60-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the support structure of Amplatz et al to be formed from a single wire-like element as taught by either Andersen et al or Shaw et al to enable the device to remain quite flexible in its compacted, inserted configuration (Shaw et al, Col. 13, lines 60-67).

8. Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz et al (US Pat. No.: 5,944,738) in view of either Andersen et al (US

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Pat. No.: 5,876,445) or Shaw et al (US Pat. No.: 6,171,329) as applied above, and further in view of Gainor et al (US Pat. No.: 2002/0169475)

In regard to Claims 60-62, Amplatz et al discloses all the limitations of the claims but fails to disclose that the membrane is made of a material with a cross section differing from that of the wire like element and formed from a weave, scrim. However, Gainor et al teaches device comprising a membrane that is made of a polyester with a cross section differing from that of a wire-like element and formed from a weave or scrim (Fig. 2). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to include a membrane that is made of a polyester with a cross section differing from that of a wire-like element and formed from a wave, scrim to prevent large particles from go through the membrane.

9. Claims 67-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz et al (US Pat. No.: 5,944,738) in view of Shaw et al (US Pat. No.: 6,171,329).

In regard to Claims 67-73, Amplatz et al discloses all the limitations of the claims but fails to disclose a positioning system.

However, Shaw et al teaches a positioning system, comprising: an advancing element (62), a guide wire and/or inner mandrel (42), at least one retaining wire (96), and an extraction wire (104); wherein a retaining wire loop is formed (Fig. 12A). The number of retaining wire and retaining wire loops are merely an obvious designed choice and within one of ordinary skill in the art.

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At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Amplatz et al and Shaw et al before him or her, to modify the system of Amplatz et al to include a positioning system comprising an advancing element, a guide wire and/or inner mandrel, at least one retaining wire, and an extraction wire; wherein a retaining wire loop is formed as taught by Shaw et al.

The suggestion/motivation for doing so would have been to facilitate and enhance the ease of delivering/retracting the implantable device (Shaw et al, Col. 3, lines 23-55)

Therefore, it would have been obvious to combine Shaw et al with Amplatz et al to obtain the invention as specified in the instant claims.

### ***Response to Arguments***

10. Applicant's arguments with respect to claims 40-63 and 65-73 have been considered but are moot in view of the new ground(s) of rejection.

The support element 2 of Shaw et al is clearly made from a single wire-like element that intercoils/interwines (Shaw et al, Figs. 6B-7B). In addition, Andersen et al teaches a support structure of an implantable device formed from a single wire-like element that interweaves/interwines (Andersen et al, Col. 8, lines 30-31).

### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**



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See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. O./  
Examiner, Art Unit 3773  
04/25/2010

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773